REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested in view of the foregoing amendments and discussion presented herein. Claims 64-67, 70-81, and 84-92 are pending in the present application. Claims 68, 69, and 82-83 have been withdrawn. Claims 93-98 have been cancelled.

1. Rejection of Claims 64-67, 69-81 and 84-92 under 35 U.S.C. § 102(b).

Claims 64-67, 69-81 and 84-92 were rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Swaminathan (U.S. No. 6,517,533) and Dann et al. (U.S. No. 5,899,932), hereinafter "Dann." Such rejections are overcome as follows:

a. Prima Facie Case Not Established in 07/24/07 Office Action

Independent method Claim 64 recites, among other steps, inserting a catheter assembly into the general proximity of the target prostate gland, placing the distal end of the inserted catheter assembly in a space between the rectum and the prostate gland, inflating an inflatable member of the catheter assembly between the prostate gland and the rectal wall, and initiating and conducting treatment of the prostate gland tissue.

Independent method Claim 79 similarly recites: placing the distal end of said inserted catheter assembly at an edge between the target tissue site and a sensitive healthy tissue or non-targeted site, inflating an inflatable member of the catheter assembly between the target tissue and non-targeted tissue to physically displace the target tissue from the non-targeted tissue, and initiating and conducting treatment of the target tissue once the inflatable member is inflated.

None of the above steps are shown in Swaminathan or Dann, nor has the Examiner provided any showing of the above steps in either of the cited references, and thus a prima facie case of anticipation has not been shown under § 102(b).

Page 2 of the present Office Action states:

> "Swaminathan discloses in figure 10, a method for treatment of the prostate gland as recited in the claims as follows: placing the distal end of a catheter (90) between the rectum and the prostate gland; inflating a balloon (98) mounted on the distal end of the catheter (90) between the prostate gland and the rectal wall…" (emphasis added).

Applicants respectfully request that the Examiner distinctly point to either a prostate gland or rectum/rectal wall, or any anatomical feature, in FIG. 10 of Swaminathan. FIG. 10 only discloses a catheter (90), and is completely absent any description of anatomy. The accompanying description for FIG. 10 (see col. 6, line 32 to col. 7, line 54) is also absent any description or reference to anatomy. Even more, Applicants failed to find any discussion anywhere in the Swaminathan reference of treating the prostate gland (a word search of the term "prostate" found no occurrences), nonetheless placing the distal end of the inserted catheter assembly in a space between the rectum and the prostate gland, as recited in Claim 64. Furthermore, no discussion was found for inflating an inflatable member to physically displace the target tissue from the non-targeted tissue, as recited in claim 79. In fact, The only description of treatment within the body that the Applicant's were able to find in Swaminathan was at col. 2 lines 24-34, stating "clinical situations may be vascular or nonvascular applications, and may include coronary or non-coronary applications."

Page 3 of the present Office Action states:

> "Dann et al. discloses in figures 2-11, a method for treatment of the prostate gland as recited in the claims as follows: placing the distal end of a catheter (32) between the rectum and the prostate gland; inflating a balloon (34) mounted on the distal end of the catheter (32) between the prostate gland and the rectal wall…" (emphasis added)

Dann discloses transurethral thermal therapy device (see Col. Lines 27-30), and FIGS 2-11 illustrate a device used (and is only capable of being used) as such. Out of "figures 2-11", only figures 5-7 and 10-11 show implementation of the device within the human anatomy, and all such figures show the treatment device (antenna 74) installed

in the urethra 10 in a treatment configuration surrounded by the prostate 14. (see also Abstract, Col. 6, lines 21-46). No other delivery method is shown or contemplated in the Dann et al reference. Because of the transurethral delivery and treatment disclosed in Dann et al., a section of prostate tissue 14 must anatomically lie between the treatment device 74 and the rectum 26 (see figures 5-7 and 10-11). In such a configuration, it would be impossible for the Dann et al. device to be inserted in a space between the rectum and the prostate gland, as this would require the device to simultaneously be in two spaced apart locations. Also, because the Dann et al. device is surrounded by the prostate 14 (target tissue) it cannot physically displace the target tissue from the non-targeted tissue. Hence, FIGS. 2-11 of Dann et al. fail to show all the cited elements of claims 64 and 79.

The Examiner has only provided a blanket reference to figures 2-11 in Dann et al. and figure 10 in Swaminathan, along with a mere recitation of the elements in the Applicant's claims, and has not provided any direction or explanation of how the individual elements of the pending claims are shown in the figures or described in the text. As such, the a *prima facie* showing of anticipation of Claims 74 and 79 has not been provided, and the rejection 64-67, 69-81 and 84-92 under § 102 is therefore improper.

b. Legal Conclusions Proposed in Examiner's "Response to Arguments" Are Not Supported by Law

Page 3 of the present Office Action states:

> "In response to applicant's argument that Swaminathan and Dann references fail to teach or suggest placing the distal end of catheter (90)(32) in space between the rectum and the prostate gland and inflating the balloon (98)(34) to displace the prostate from the rectal wall and to displace the target tissue from the non-targeted tissue, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claims." (emphasis added)

Applicants object to the above highlighted statement on a number of levels. First, the Examiner has provided no support (either from the M.P.E.P. or established case law), for such a profound and sweeping rule that clearly contradicts a number of well-established court decisions and statutes.

Applicants remind the Examiner that the pending claims are all method claims. As such, structural limitations are not required, and it is generally prudent practice to refrain from including structural limitations in process steps. However, by stating that "a recitation of the intended use of the claimed invention must result in a structural difference," the Examiner is now requiring that structural limitations be imported into the claimed method steps, otherwise there would be no way to distinguish from the structural aspects of the recited reference.

If the above statements proposed by the Examiner were true, then method claims would be obsolete, as they would have little difference from apparatus claims. The Examiner's above proposed statements would also negate the new use doctrine as held by the Federal Circuit (see *In re Schoenwald*, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992); *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 875, 228 USPQ 90, 99 (Fed. Cir. 1985) ("Even if a composition is old, a process using a known composition in a new and unobvious way may be patentable.") (emphasis added). If the Examiner's statement "if the prior art structure is capable of performing the intended use, then it meets the claim," were true, then no new use claim would be patentable, because the old composition will always be capable of performing the new use. Again, the Examiner's above statements are in contradiction to present law.

Even assuming *arguendo* that the Examiner's statements on page 3 were to be valid law, the structure shown in the cited references is different from the structure of the present invention, and not capable of performing the steps or "intended use" Claims 64 and 79. The present invention teaches positioning and inflation of the inflatable member between sensitive, non-target tissue (rectum) and the and target prostate gland to create separation between the prostate gland and the rectum, allowing isolation of

treatment to the prostate gland alone. The above-mentioned steps are instrumental for successful treatment of the prostate gland, as the prostate is located adjacent sensitive organs such as the rectum, of which thermal treatment may be damaging. The Dann device shows an anchoring balloon 34 distal to the treatment device (antenna 74) (see FIGS. 5-7). This retention balloon 34 is configured to be expanded in the bladder 12 to retain the device just below the neck 11 of the bladder 12. If such device were to be taken out of its functional context shown in Dann et al. (i.e. transurethral delivery), and positioned between the rectum 12 and prostate 14, it could not separate the target tissue (prostate 14) from the non target tissue (rectum) because the balloon 34 is located distal the treatment region (antenna 74).

c. Dependent Claims 65-67, 69-78, 80-81, and 84-92

Claims 65-67, 69-78, 80-81, and 84-92, being dependant from allowable base Claims 64, and 79, are therefore also allowable. However, Claims 65-67, 69-78, 80-81, and 84-92, also recite limitations that are not found in the cited reference.

For example, Claim 72 recites, among other elements, inflating or circulating a fluid through the catheter assembly that is below the normal body temperature during the treatment of the prostate gland by thermotherapy, wherein the treatment comprises heating the prostate gland. This allows the fluid to cool surrounding tissue during thermal therapy treatment that is heating the target site. Swaminathan, in contrast, discloses a cryotherapy device that uses a liquid to cryogenically cool and treat surrounding tissue.

Page 3 of the present Office Action states that "Swaminathan disclosed the step of circulating and replacing fluid through lumen (96, 100, 108) higher normal body temperature during treatment in which capable of being heated the prostate gland as recited in the claim." The above argument, besides being unintelligible, does not point to any therapeutic heating of a target tissue, particularly since the device is configured for cryotherapy, e.g. cooling tissue. (see col. 1, lines18-20, "Cryotherapy, the therapeutic use of cold, is known in the medical field."). Again, the Examiner's

statement talks to "capable." Even if the cryotherapy device of Swaminathan were shown to be capable of heating tissue (Examiner has shown no support for such an assertion), such capability would still not, in itself, anticipate a method claim having novel steps as recited in Claim 72.

Claims 73, 84, and 88 have not even been mentioned by the Examiner, nonetheless providing a prima facie case of anticipation by pointing to the requisite limitations in the cited art. Each of these claims also recite novel and unobvious subject matter not shown in the cited references.

For example, Claim 73 recites the steps of inflating an inflatable member with a gas to physically displace the prostate from the rectal wall and form an acoustic barrier to protect rectal wall or surrounding tissue, and initiating and completing ultrasonic treatment of the prostate gland. As explained above, Swaminathan does not mention treatment of the prostate, particularly displacing the prostate from the rectal wall. In addition, neither of the steps of forming an acoustic barrier nor initiating ultrasonic treatment are taught or suggested by the cited art. Also, the transurethral catheter of Dann is incapable of displacing the prostate from the rectal wall to form an acoustic barrier, as it is configured for insertion in the urethra, and the retention balloon is configured to anchor at a location away (i.e. at bladder neck 11) from the treatment site. Furthermore, Dann does not discuss ultrasonic treatment, as it uses microwave energy to deliver therapy.

Claim 84 recites, among other elements, inflating an inflatable member with a gas to physically displace the target tissue from the sensitive tissue and form an acoustic barrier, initiating and completing ultrasonic treatment of the target tissue, and replacing the gas within the inflatable member and the catheter assembly with a liquid after the conclusion of the ultrasonic treatment of the target tissue. As explained above, formation of an acoustic barrier and use of ultrasonic treatment are not taught nor suggested by Swaminathan. In addition, Swaminathan is void any discussion of use of a gas to physically displace target tissue from sensitive tissue, nor replacing the gas

with a liquid.

Independent method Claim 88 recites, among other steps, placing the distal end of an inserted catheter assembly in a space between the rectum and the prostate gland, and inflating an inflatable member of the catheter assembly between the prostate gland and the rectal wall. As mentioned above with respect to Claim 64, Swaminathan is absent any discussion of treating the prostate gland, nonetheless placing the distal end of the inserted catheter assembly in a space between the rectum and the prostate gland. Furthermore, Dann only discloses the transurethral placement of a delivery device and conducting treatment when the device is surrounded by the prostate gland. In addition, the expandable retention balloon 34 is only shown or configured to be expanded in the bladder, and thus fails to teach or suggest inflating an inflatable member between the prostate gland and the rectal wall.

Accordingly, the rejection of Claims 65-67, 69-78, 80-81, and 84-92 under § 102 in view of Swaminathan and Dann et al. is improper, and should be removed.

2. Amendments Made Without Prejudice or Estoppel.

Notwithstanding the amendments made and accompanying traversing remarks provided above, Applicants have made these amendments in order to expedite allowance of the currently pending subject matter. However, Applicants do not acquiesce in the original ground for rejection with respect to the original form of these claims. These amendments have been made without any prejudice, waiver, or estoppel, and without forfeiture or dedication to the public, with respect to the original subject matter of the claims as originally filed or in their form immediately preceding these amendments. Applicants reserve the right to pursue the original scope of these claims in the future, such as through continuation practice, for example.

3. Conclusion.

Based on the foregoing, Applicants respectfully request that the various grounds for rejection in the Office Action be reconsidered and withdrawn with respect to the presently amended form of the claims, and that a Notice of Allowance be issued for the

present application to pass to issuance.

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Respectfully submitted,

/M. Robyn Carrillo/

John P. O'Banion, Reg. No. 33,201
Robert F. Kramer, Reg. No. 51,242
M. Robyn Carrillo, Reg. No. 47,474
O'BANION & RITCHEY LLP
400 Capitol Mall, Suite 1550
Sacramento, CA 95814
(916) 498-1010